phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biological product AVASTIN (bevacizumab). AVASTIN, used in combination with intravenous 5-fluorouracil-based chemotherapy, is indicated for first-line treatment of patients with metastatic carcinoma of the colon or rectum. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for AVASTIN (U.S. Patent No. 6,054,297) from Genentech, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 8, 2005, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of AVASTIN represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for AVASTIN is 2,551 days. Of this time, 2,401 days occurred during the testing phase of the regulatory review period, while 150 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: March 5, 1997. The applicant claims February 3, 1997, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 5, 1997, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262)*: September 30, 2003. The applicant claims August 29, 2003, as the date the biologics license application (BLA) for AVASTIN (BLA 125085/0) was initially submitted. The applicant claims this is the date it submitted the first unit of BLA 125085/0, which was submitted in several units as part of a rolling application submission procedure. It is FDA's position that the approval phase begins when the marketing application is complete. A review of FDA records reveals that the final module of the BLA 125085/0 was submitted on September 30, 2003, which is considered to be the complete marketing application initially submitted date.

3. *The date the application was approved*: February 26, 2004. FDA has verified the applicant's claim that BLA 125085/0 was approved on February 26, 2004.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 307 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by November 20, 2006. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by March 19, 2007. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 1, 2006.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E6–15555 Filed 9–19–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005E–0234]

Determination of Regulatory Review Period for Purposes of Patent Extension; MACUGEN

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for MACUGEN and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA approved for marketing the human drug product MACUGEN (pegaptanib sodium). MACUGEN is indicated for the treatment of neovascular (wet) age-related macular degeneration. Subsequent to this

approval, the Patent and Trademark Office received a patent term restoration application for MACUGEN (U.S. Patent No. 6,051,698) from Gilead Sciences, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated June 28, 2005, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of MACUGEN represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for MACUGEN is 2,312 days. Of this time, 2,128 days occurred during the testing phase of the regulatory review period, while 184 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: August 21, 1998. The applicant claims August 20, 1998, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 21, 1998, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: June 17, 2004. The applicant claims March 17, 2004, as the date the new drug application (NDA) for MACUGEN (NDA 21–756) was initially submitted. The applicant claims this is the date it submitted the first module of NDA 21–756, which was submitted in several modules as part of a rolling NDA submission procedure. It is FDA's position that the approval phase begins when the marketing application is complete. A review of FDA records reveals that the final module of the marketing application was submitted on June 17, 2004, which is considered to be the NDA initially submitted date.

3. *The date the application was approved*: December 17, 2004. FDA has verified the applicant's claim that NDA 21–756 was approved on December 17, 2004.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 990 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by November 20, 2006. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by March 19, 2007. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 1, 2006.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E6–15556 Filed 9–19–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0303]

Draft Guidance for Industry on Public Availability of Labeling Changes in "Changes Being Effected" Supplements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Public Availability of Labeling Changes in 'Changes Being Effected' Supplements." The guidance announces to holders of a new drug application (NDA), an abbreviated new drug application (ANDA), or a biologics license application (BLA), who intend to submit a "Changes Being Effected" supplement (CBE supplement) to make a postapproval labeling change, that FDA will make labeling revisions identified in a CBE supplement publicly available upon receipt of the supplement by FDA. The guidance does not have any bearing on supplements that relate to chemistry, manufacturing, and controls changes, nor does it expand the circumstances in which an ANDA holder may effect labeling changes via a CBE supplement.

DATES: Submit written or electronic comments on the draft guidance by November 20, 2006. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Meredith S. Francis, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Public Availability of Labeling Changes in 'Changes Being Effected' Supplements." FDA has begun an initiative to facilitate computerized access to drug information by consumers, pharmacists, and health care providers so that they will have faster and more comprehensive access to drug information. As part of this initiative, the agency has been involved in the development of a computerized repository of a broad array of drug information, known as "DailyMed." Among other things, DailyMed contains the information referred to as "content of labeling," which includes all the information found in prescription drug labeling and over-the-counter (OTC) drug facts labeling, including all text, tables, and figures (see 21 CFR 314.50(l)(1)(i)). To maximize its ability to serve as a useful resource to consumers, pharmacists, and health care providers, DailyMed must contain the